MEDPAC Medicare Payment Advisory Commission

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August 30, 2011

Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1525-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: File code CMS-1525-P

Dear Dr. Berwick:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit comments on CMS's proposed rule entitled: *Medicare and Medicaid programs: Hospital outpatient prospective payment; ambulatory surgical center payment; hospital value-based purchasing program; physician self-referral; and provider agreement regulations on patient notification requirements* [CMS-1525-P]. We appreciate your staff's ongoing efforts to administer and improve the payment systems for hospital outpatient departments and ambulatory surgical centers (ASCs), particularly considering the agency's competing demands.

As you know, the outpatient prospective payment system (OPPS) classifies services provided in outpatient departments into ambulatory payment classification (APC) groups. Each APC group has a relative weight, which is an indexed measure of the resources needed to furnish a service. The OPPS determines payment rates for APC groups as the product of the relative weights and a conversion factor. The ASC payment system largely uses the APCs and relative weights from the OPPS, but uses a different conversion factor to obtain payment rates. This proposed rule is similar to its predecessors in the sense that it documents changes in the composition of some APC groups and proposes changes to the relative weights based on analysis of claims and cost report data. The rule also estimates the calendar year 2012 update to the conversion factors in the OPPS and ASC payment systems.

This rule also proposes to:

- Provide substantial proportional increases to the payment rates for OPPS covered services provided by the 11 cancer specialty hospitals.
- Repeat the policy established in 2010 of redistributing estimated pharmacy overhead costs from drugs that are packaged with an associated procedure to drugs that are paid separately. The intent of this policy is to improve how accurately payments for separately paid drugs reflect the hospitals' costs of acquiring and handling them.
- Request comment on four options for determining the wage index used to adjust OPPS payments for regional differences in input costs.
- Create composite APC 8009, cardiac resynchronization therapy with defibrillator. This composite APC provides a single payment when two services are provided on the same day: Current procedural terminology (CPT) code 33225 (insertion of a pacing electrode) and CPT code 33249 (insertion or repositioning of electrode leads for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator).
- Add several quality measures for payment determination in 2013, 2014, and 2015 under the hospital outpatient quality reporting program (Hospital OQR Program).
- Adopt eight quality measures for ambulatory surgical centers (ASCs) for payment determination in 2014 under the ASC Quality Reporting Program.
- Finalize various technical policies for the FY 2014 Inpatient Hospital Value-Based Purchasing (VBP) program.

We focus our comments on these seven topics.

Payment rate issues: Proposed 2012 update and adjustment to payment rates for cancer hospitals

We comment on two issues in this proposed rule regarding the OPPS payment rates:

- Update the OPPS conversion factor by 1.5 percent. This proposed update is based on an estimated increase in the hospital market basket of 2.8 percent minus a 1.2 percentage point deduction for multifactor productivity and an additional deduction of 0.1 percentage point specified in the Patient Protection and Affordable Care Act of 2010 (PPACA).
- Provide hospital-specific increases to OPPS payments rates for the 11 hospitals classified as cancer hospitals under section 1886(d)(1)(B)(v) of the Social Security Act. The purpose of this policy is to increase payment rates so that the payment to cost ratio (PCR, a measure of profitability) for each cancer hospital is equal to the average PCR for all other hospitals. The proposed adjustments to the cancer hospital's payment rates range from 10.1 percent to 61.8 percent and would average 39.3 percent across all cancer hospitals.[1] To make these adjustments budget neutral in the OPPS, CMS will reduce the OPPS payment rates for all other hospitals by 0.7 percent.

[1] This policy also would result in reduced hold-harmless payments to cancer hospitals. CMS estimates that the net effect of the higher payment rates and lower hold-harmless payments would be an increase in aggregate OPPS payments to cancer hospitals of about 9 percent.

Comments

Both proposed policies reflect current law established in PPACA. We understand that CMS is required to implement the policies as stated in PPACA and commend CMS for their work. However, we want to emphasize that we have previously stated positions on these policies that differ from those in PPACA. In our March 2011 Report to the Congress, we recommended that the OPPS conversion factor be updated by 1.0 percent in 2012.[2] In our comment letter on the 2011 proposed rule, we expressed reservations about the proposed adjustments to the OPPS payment rates to cancer hospitals and discussed alternatives that we believe would improve the policy.[3]

Pharmacy overhead costs and setting payments for separately paid drugs

In the OPPS, CMS provides separate payment for drugs whose daily costs exceed a set threshold. For 2012, CMS has proposed to set this threshold at $80 per day. For drugs whose costs do not exceed this threshold, CMS packages their costs into the payment rate of the applicable outpatient service.

A longstanding issue that CMS has attempted to address is how to accurately reimburse hospitals for the pharmacy overhead costs they incur from dispensing the separately paid drugs. A group of industry stakeholders—some cancer hospitals, some pharmaceutical manufacturers, and some hospital and professional associations—argued that the method that CMS used to set payment rates for separately paid drugs from 2006 through 2009 overpaid pharmacy overhead costs for packaged drugs and underpaid them for separately paid drugs. Starting in 2010, CMS addressed this issue by redistributing about $200 million of the pharmacy overhead costs of packaged drugs to separately paid drugs. For 2012, this policy would result in payments rates for separately paid drugs equal to each drug's average sales price (ASP) plus 4 percent.

Comments

Even though we believe this redistribution of overhead costs results in payments that more accurately reflect the overhead costs of separately paid drugs in aggregate, we have reservations about setting payments rates as a percentage of each drug's ASP because it implicitly assumes pharmacy overhead costs are the same proportion of total costs for all drugs. We show in our June 2005 Report to the Congress that pharmacy overhead costs as a percentage of total costs vary widely across drugs.[4] Consequently, as an alternative method for accurately paying for drugs, MedPAC has recommended that CMS collect data on hospitals' pharmacy overhead costs separately from drug acquisition costs. These data could be used to create separate payments to hospitals for pharmacy overhead and drug acquisition costs. In a previous rule, CMS rejected this recommendation, arguing that it would reduce the amount of packaging in the OPPS (which CMS

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[2] Medicare Payment Advisory Commission. 2011. *Report to the Congress: Medicare payment policy.*
[3] MedPAC comment letter on the proposed rule for calendar year 2011 for the outpatient PPS, August 30, 2010.
[4] Medicare Payment Advisory Commission. 2005. *Report to the Congress: Issues in a modernized Medicare program.*

has been trying to increase in recent years) and because of comments stating that this policy would be administratively burdensome for hospitals.[5]

CMS has also addressed a recommendation from the Advisory Panel on APC groups that CMS should exclude from its method for setting payment rates for separately paid drugs data from hospitals that participate in the 340B federal drug pricing program.[6] The 340B hospitals are generally hospitals that serve a disproportionate share of low-income patients and receive disproportionate share payments under the inpatient prospective payment system (IPPS). These hospitals may acquire outpatient drugs and biologicals at prices that are substantially below ASP. The panel's concern is that use of data from 340B hospitals in the ratesetting method results in estimated costs for separately paid drugs that are below the costs incurred by non-340B hospitals.

CMS has rejected this recommendation in previous years and proposed to reject it again for 2012. Implementing this recommendation would increase payment rates for separately paid drugs. To maintain budget neutrality in the OPPS, CMS would have to reduce payment rates for all other services in the OPPS. These adjustments would result in payments being redistributed to separately paid drugs from other services. CMS does not believe this redistribution would be appropriate.

Consistent with our comments on the 2010 and 2011 proposed rules, we encourage CMS to consider excluding data from 340B hospitals from the ratesetting method.[7] Analysis by Direct Research LLP indicates that exclusion of the 340B hospitals would increase CMS's estimates of the cost of separately paid drugs by about 3.5 percent above the estimate obtained when the 340B hospitals are included in the ratesetting.[8] We believe the effect of whether the 340B hospitals are included in the ratesetting is not trivial and excluding the 340B hospitals would result in payment rates for separately paid drugs that more accurately reflect the costs incurred by non-340B hospitals.

Proposed options for addressing issue of rural floor in wage indexes

CMS adjusts 60 percent of payments for services in the OPPS for regional differences in labor and labor-related costs. Although not legislatively required to do so, CMS has always applied the wage indexes used in the IPPS to the OPPS payments. In this proposed rule, CMS expresses concern over continued use of the wage indexes from the IPPS. The source of this concern is the requirement that within a state, wage indexes for hospitals in urban locations cannot have a wage index below the average wage index for rural hospitals (often called the 'rural floor'). CMS identifies a specific case where a critical access hospital (CAH) converted back to an IPPS hospital, causing IPPS payment rates for the urban hospitals in the state to increase by 8 percent.

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[5] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2009. Medicare program: Proposed changes to the hospital outpatient prospective payment system and CY 2010 payment rates; proposed changes to the ambulatory surgical center payment system and CY 2010 payment rates.
[6] The Advisory Panel on APC groups advises CMS about the clinical integrity of APCs and their payment weights.
[7] MedPAC comment letter on the proposed rule for calendar year 2011 for the outpatient PPS, August 30, 2010. MedPAC comment letter on the proposed rule for calendar year 2010 for the outpatient PPS, August 28, 2009.
[8] Hogan, C. 2008. Memorandum summarizing analysis of 340B hospitals.

A provision in PPACA requires such adjustments to be budget neutral on a national basis, and this situation required the hospital wage indexes for all other IPPS hospitals to be reduced by 0.62 percent, which reduces their Medicare payments.

Comments

In response to CMS' concern, we reiterate our recommendations on wage index reform in our June 2007 Report to the Congress.[9] These recommendations would repeal the existing hospital wage index statute, including reclassifications and exceptions, and give the Secretary the authority to establish a new wage index system. Our recommendations specified that a new hospital compensation index should be established so that it:

- Uses wage data from all employers and industry-specific occupational weights;
- Is adjusted for geographic differences in the ratio of benefits to wages;
- Is adjusted at the county level and smooths large differences between counties; and
- Is implemented so that large changes in wage index values are phased in over a transition period.

The Institute of Medicine (IOM) has reached a similar conclusion in a recent report, which recommends a new wage index system based on Bureau of Labor Statistics data with a method for smoothing differences in wage indexes across adjacent payment areas. The new system "is intended to replace the system of geographic reclassification and exceptions that is currently in place."[10] We encourage CMS to consider the MedPAC and IOM recommendations.

Instead of replacing the current wage index system, in this proposed rule CMS is seeking public comment on four possibilities for addressing the rural floor in the OPPS wage indexes:

1. Adopt the IPPS wage index for the OPPS in its entirety, including the rural floor.
2. Adopt the IPPS wage index for the OPPS in its entirety except when a small number of hospitals set the rural floor for the benefit of all other hospitals in the same state.
3. Adopt the IPPS wage index for the OPPS in its entirety except apply rural floor budget neutrality within each state instead of nationally.
4. Adopt another decision rule for when the rural floor should not be applied in the OPPS when we have concerns about disproportionate impact.

In comments on past proposed rules for the IPPS, MedPAC has expressed reservations about the rural floor.[11] In our comment on the 2009 IPPS proposed rule, we expressed support for the idea of applying budget neutrality to the rural floor at the state level, which is consistent with the third option listed above. Under that option, when a rural hospital makes a change in status that raises the rural floor, only wage indexes in the same state would be lowered to satisfy budget neutrality.

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[9] Medicare Payment Advisory Commission. 2007. *Report to the Congress: Promoting greater efficiency in Medicare.*
[10] Institute of Medicine, 2011. *Geographic Adjustment in Medicare Payment: Phase I: Improving Accuracy.* The National Academy Press, Washington DC.
[11] MedPAC comment letter on the proposed rule for fiscal year 2009 for acute care hospitals, June 10, 2008; MedPAC comment letter on the proposed rule for fiscal year 2012 for acute care hospitals, June 17, 2011.

This option would preclude the case CMS raised of a single CAH in a rural area of a state becoming an IPPS hospital, which resulted in increased hospital payments in the state. In addition, it would reduce the incentive for all rural hospitals other than the highest cost hospitals to reclassify out of a state to raise a state's rural floor wage index. Consequently, a state-level budget neutrality provision would improve fairness and reduce opportunities to manipulate the wage index system for financial benefit. Therefore, in the absence of replacing the wage index system (MedPAC's recommended approach), we support the third option above: Adopt the IPPS wage index for the OPPS in its entirety except apply rural floor budget neutrality within each state instead of nationally.

Composite APC 8009

For calendar year 2008, CMS expanded the extent to which services are packaged together into a single payment rather than separate payments for individual services. As part of this expansion, CMS identified some services that had previously been paid separately but are often provided in the same outpatient visit. The end result was the creation of "composite APCs", which creates a single payment if two or more services with separate payment rates are provided in the same outpatient visit. Over time, CMS has added to the list of composite APCs, which currently stands at nine.

For calendar year 2012, CMS has proposed to add composite APC 8009, cardiac resynchronization therapy with defibrillator composite. This APC provides a single payment if two procedures—CPT code 33225 (insertion of a pacing electrode) and CPT code 33249 (insertion or repositioning of electrode leads for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator)—are performed on a patient on the same day. According to CMS, claims data indicate that these two procedures are frequently performed together. By creating a composite APC, CMS is able to use the claims where these two services are provided together to create a reliable estimate of the cost of providing them in the same outpatient visit. In the OPPS, obtaining reliable cost data leads to payment rates that are stable over time and that accurately reflect the cost of providing these services. Also, a number of sources have commented that because insertion of a pacing electrode (CPT code 33225) is usually provided along with insertion of a pacemaker or implantable cardioverter-defibrillator (CPT code 33249), CMS does not have many claims upon which to estimate the cost of inserting a pacing electrode by itself, resulting in unreliable cost estimates and payment rates that vary widely from year to year.

Comments

Because creation of this composite APC apparently would provide more stable payments and because MedPAC has consistently supported larger payment packages in the OPPS, we support the creation of APC 8009 for calendar year 2012.

Hospital Outpatient Quality Reporting Program

CMS has implemented a quality reporting system for hospital outpatient services, now known as the Hospital Outpatient Quality Reporting (Hospital OQR) Program (formerly called the Hospital Outpatient Quality Data Reporting Program, or HOP QDRP). A hospital's participation in the Hospital OQR Program is voluntary, but Section 1833(t)(17) of the Social Security Act requires a two percentage point reduction in a hospital's annual OPPS payment update factor if the hospital fails to report all of the hospital outpatient quality measures specified by the Secretary for a given prior year (for example, hospitals must successfully report on 15 quality measures in 2011 in order to receive a full OPPS payment update in 2012). In July 2010, CMS began public reporting on Medicare's Hospital Compare website of each participating hospital's outpatient quality measures along with the hospital's inpatient quality measures.

As with the inpatient quality reporting program—which began with 10 measures in 2004 and is slated to reach 76 measures in 2015—the number of measures used in the Hospital OQR Program has expanded significantly, as shown in Table 1:

Table 1. Number of Hospital OQR program measures by data source, 2009-2015

OPPS payment determination year	Number of measures by data source				
	Total	Medical charts sample	Medicare claims	Structural reporting	NHSN
2009	7	7	0	0	0
2010	11	7	4	0	0
2011	11	7	4	0	0
2012	15	7	7	1	0
2013	23	14	7	2	0
2014 proposed	32	20	7	4	1
2015 proposed	33	20	7	4	2

Note: NHSN (National Healthcare Safety Network administered by Centers for Disease Control and Prevention).

For the 2009 OPPS payment update, all seven measures required hospitals to extract specified data from a sample of patient medical records, including five measures of emergency department (ED) care processes for acute myocardial infarction (AMI) and two measures of perioperative surgical care processes. For the 2010 update, CMS added four measures of potential overuse of specific imaging services. These measures are calculated from Medicare claims data and therefore do not require medical record data extraction and submission by hospitals. CMS did not add any measures for the 2011 payment update determination but maintained the same 11 measures as the previous year.

For the 2012 payment update determination, CMS added three more claims-based measures of potential imaging service overuse and one structural measure related to whether a hospital has an EHR system that allows for direct electronic transmission of laboratory data in the EHR. Last year, CMS finalized its proposal to require 23 measures for the 2013 payment update, including seven new measures that require hospitals to extract data from patient medical charts to assess the quality of various aspects of ED care, and one new structural measure of a hospital's capability to track patients' clinical results between outpatient visits.

In this year's proposed rule, CMS proposes to add nine new measures—for a total of 32—for the 2014 payment update determination. The new metrics include a healthcare-associated infection (HAI) measure specific to surgical site infections (SSIs); five diabetes care measures and one cardiac care measure—all six of which would require hospitals to extract data from a sample of patient medical records—and two structural measures including attestation of the facility's use of a safe surgery checklist and reporting by the facility of its volume of selected outpatient surgical procedures across all (i.e., not only Medicare) patients.

For the SSI measure, CMS proposes that hospitals would use the CDC's National Healthcare Safety Network (NHSN). NHSN data collection occurs via a Web-based tool hosted by CDC that is provided free of charge to providers. According to the proposed rule, 28 states currently require hospitals to report HAIs using NHSN, and the CDC provides support to more than 4,000 hospitals that are using NHSN. For SSI reporting through the NHSN, hospitals are required to select at least one procedure category from a list of categories maintained by the CDC and then collect data on all patients who received any procedure in that category for at least one month. Hospitals must look for SSIs in patients who receive one of the selected procedures for at least 30 days after the procedure (or 1 year if an implant is left in place). The surveillance process should cover both the pre- and post-discharge period and should include the following methods: direct examination of patients' wounds during follow-up visits to clinics or physicians' offices, review of medical records, surveys of surgeons, and surveys of patients. Hospitals must complete a form for each patient who receives one of the selected procedures and a form for each patient who has an SSI.

CMS proposes to add another HAI-related measure for the 2015 payment update determination, influenza vaccination coverage among the hospital's healthcare personnel, which also would be reported through the CDC's NHSN.

Comments

The Commission strongly supports quality measurement and pay-for-performance (or value-based purchasing) in Medicare, but we are concerned that the proposed growth in the number of outpatient quality measures—particularly those that require hospitals to extract data from patient

medical charts—is not consistent with our criterion that collecting and analyzing quality measurement data should not be unduly burdensome for either the provider or CMS.[12] After an initial set of seven chart-based measures, CMS added seven more for the 2013 payment update determination and now proposes to add six more for the 2014 and 2015 updates, for a total of 20 chart-based outpatient measures. This effort for hospitals and CMS on the outpatient side would be in addition to the 22 chart-based inpatient measures CMS plans to require for the FY 2014 IPPS update, with 36 chart-based inpatient measures required for 2015.

We also urge CMS to analyze the estimated costs to hospitals for fully participating in the inpatient and outpatient quality reporting programs each year, and publish the results of this analysis in the next OPPS final rule. The OPPS proposed rule includes estimates of the average and total number of hours it would take hospitals to meet the program's reporting requirements, but there is no information on the estimated average or total costs hospitals must incur to meet the quality reporting requirements.

Beyond the administrative costs, we noted in our March 2011 comment letter on the Hospital Value-Based Purchasing (VBP) program proposed rule that a growing body of literature suggests at least some of the clinical process measures Medicare currently uses to measure inpatient hospital quality capture only a small proportion of the observed variation in hospital mortality rates or they have little or no association with aggregate mortality or readmission rates.[13] These findings suggest that the benefits from continuing to measure these processes may be outweighed by the costs of doing so, and may impose opportunity costs on providers' ability to engage in potentially more productive quality improvement activities.

In light of this research, we encourage CMS to consider a moratorium on adding any new process of care measures that require medical chart data abstraction until the agency evaluates the ability of each measure to capture meaningful differences in health outcomes.

We support CMS's proposal to align the measurement of surgical site infections across the hospital inpatient, hospital outpatient, and ambulatory surgical center (ASC) settings (the proposed rule's ASC SSI measure is discussed below). When fully implemented, Medicare beneficiaries and policymakers would be able to compare rates of these preventable healthcare-associated infections across all of the settings of care where the same surgical procedures are performed.

We also support CMS's proposal to add a new structural measure for the 2014 payment update determination on the hospital outpatient department's use of a safe surgery checklist. A safe surgery checklist would help ensure that safe practices are performed prior to administration of anesthesia, prior to incision, and prior to the patient leaving the operating room. Because CMS also proposes to add this measure to the ASC quality reporting program, adding it to the hospital OQR program would align measures across these settings. Because hospitals would report whether they used a safe surgery checklist via a web-based tool, we do not expect that this measure would impose a substantial administrative burden on them.

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[12] Medicare Payment Advisory Commission. 2005. *Report to the Congress: Medicare payment policy.*

[13] MedPAC comment letter on proposed rule for Medicare Hospital Value-Based Purchasing Program, March 4, 2011.

Lastly, the Commission has supported capturing data on patients' perceptions of their care as an important component of quality measurement, as long as the measures are clinically relevant such as evaluating the clarity and thoroughness of provider-patient communication. To this end, we would support Medicare's use of a patient experience survey in the hospital outpatient setting. Such a survey could be modeled after the existing Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys for clinicians and groups and the CAHPS Surgical Care Survey.

ASC policy and payment recommendations

CMS proposes to maintain its policy of not requiring ASCs to submit cost data because the agency does not use ASC cost data to set or revise payment rates. CMS also expresses concern that such a requirement could be administratively burdensome for ASCs. In the Commission's March 2011 Report to the Congress, we recommended that the Congress should implement a 0.5 percent increase in the payment rates for ASC services in 2012, concurrent with requiring ASCs to submit cost and quality data to CMS. We appreciate CMS's concern that requiring ASCs to submit cost data may be administratively burdensome for some ASCs, but the agency should develop a streamlined process for ASCs to submit such data, as described below. Cost data from ASCs would enable analysts to determine the costs of an efficient provider, which would help inform decisions about the ASC payment update. Cost data also are needed to examine whether an alternative input price index would be an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed.

We understand CMS's concern that requiring ASCs to submit cost data may impose a burden on ASCs. Although ASCs are generally small facilities that may have limited resources for collecting cost data, businesses such as ASCs typically keep records of their costs for filing taxes and other purposes. Moreover, other small providers submit cost data to CMS, including home health agencies and hospices. To minimize the burden on CMS and ASCs, CMS should create a streamlined process for ASCs to submit cost data. One such mechanism could be annual surveys of a random sample of ASCs. Another approach would be cost reports from all ASCs that are more streamlined than hospital cost reports but still have sufficient information to assess the adequacy of ASC payments and develop an ASC market basket.

CMS proposes to increase ASC payments in 2012 by 0.9 percent. This proposed update is based on CMS's estimate of a 2.3 percent increase in the consumer price index for all urban consumers (CPI–U) minus a 1.4 percent deduction for multifactor productivity growth. CMS believes that it has discretion to select the basis for updating ASC payments and has decided to base updates on the CPI-U. PPACA requires that the update be reduced by a productivity adjustment. As noted above, we recommended an update of 0.5 percent for ASC payments in 2012. This recommendation was based on our finding that most of the available indicators of payment adequacy for ASC services were positive, the lack of data on the cost and quality of ASC services, and our concerns about the potential effect of ASC growth on overall program spending. Therefore, we urge CMS to increase ASC payments by 0.5 percent in 2012.

Reporting of ASC quality data

Section 109(b) of the Tax Relief and Health Care Act of 2006 authorizes, but does not mandate, the Secretary to require ASCs to submit data on quality measures and to reduce the annual payment update by 2.0 percentage points in a subsequent year for ASCs that fail to do so. In prior final rules, CMS postponed requiring ASCs to submit quality data. In this year's proposed rule, CMS proposes to establish an ASC Quality Reporting Program. Under this program, ASCs would be required to submit quality data in 2012. Although ASCs that do not submit quality data would have their payments reduced in 2014, CMS does not propose to adjust ASC payments on the basis of facilities' performance on the quality measures. CMS recently submitted a plan to the Congress to implement a VBP program for ASCs that would reward high-performing facilities. However, CMS lacks the statutory authority to implement such a program. In a separate comment letter, the Commission states its views about CMS's plan to implement a VBP program for ASCs. In this comment letter, we focus on CMS's proposal to establish an ASC Quality Reporting Program (QRP).

In the proposed rule, CMS outlines the following principles for the ASC QRP:

- The program should use a mix of structural, process of care, outcomes, and patient experience measures.
- Measures should be aligned across public reporting and payment systems under Medicare and Medicaid.
- The collection of information should minimize the burden on providers.
- To the extent possible, measures should be endorsed by a national, multi-stakeholder organization.

CMS proposes three sets of measures for the ASC QRP that would be used to determine payments in 2014, 2015, and 2016, respectively. As with the hospital OQR program, the agency is proposing measure sets for multiple years to assist ASCs in planning for future reporting requirements and quality improvement activities.

For the 2014 payment update determination, CMS proposes to require that ASCs submit data on the following eight measures:

- Seven claims-based measures endorsed by the National Quality Forum (data submission on these measures would begin in 2012)
    - Patient burn
    - Patient fall in the ASC
    - Wrong site, wrong side, wrong patient, wrong procedure, wrong implant[14]

[14] MedPAC comment letter on the *Report to Congress: Medicare ambulatory surgical center value-based purchasing implementation plan*, August 30, 2011.

  - Hospital transfer or admission upon discharge from the ASC
  - Prophylactic intravenous (IV) antibiotic timing
  - Appropriate surgical site hair removal
  - Selection of prophylactic antibiotic: First or second generation cephalosporin
- Surgical site infection rate, which would be reported through the NHSN; data submission on this measure would begin in 2013.

For the 2015 payment update determination, CMS proposes to retain the prior year's measures and add two structural measures:

- Safe surgery checklist use
- ASC facility volume data for selected procedures

ASCs would submit data on these measures in 2013 through a Web-based tool.

For the 2016 payment update determination, CMS proposes to retain the prior year's measures and add one new measure: Influenza vaccination coverage among healthcare personnel. ASCs would report this measure through the NHSN from October 1, 2013, to March 31, 2014.

In addition, CMS asks for comment on several additional measurement areas that could be included in the future, such as:

- Patient experience measures;
- Procedure specific measures for cataract surgery, colonoscopy, and endoscopy; and
- Measures of anesthesia-related complications.

Comments

The Commission supports collecting quality data from ASCs and eventually rewarding improvements in quality made by ASCs through the payment system. Quality data would enable CMS to assess ASCs' performance and allow beneficiaries to compare providers on the basis of quality. The ASC QRP could also become the foundation for a VBP program, which was the case for the Medicare hospital inpatient VBP program. The QRP should include a relatively small set of measures to reduce the burden on ASCs and CMS, and the measure set should primarily focus on clinical outcomes because Medicare's central concern should be improving outcomes across all ASCs and over time. The program should also include some clinical process, structural, and patient experience measures.

For the first phase of the QRP, CMS should adopt the following five outcomes measures and two process measures:

- Patient burn (outcome)
- Patient fall in the ASC (outcome)
- Wrong site, wrong side, wrong patient, wrong procedure, wrong implant (outcome)
- Hospital transfer or admission after an ASC procedure, whether the patient is transferred directly to the hospital from the ASC or admitted to the hospital after returning home from the ASC procedure (outcome)
- Prophylactic IV antibiotic timing (process)
- Selection of prophylactic antibiotic: First or second generation cephalosporin (process)
- Surgical site infection rate (outcome)

CMS should not adopt the proposed measure of appropriate surgical site hair removal for the ASC QRP because the agency has decided to suspend data collection for this measure under the hospital inpatient quality reporting (IQR) program. CMS suspended data collection for this measure because it has a high level of adherence nationwide, with little variability among hospitals, and doing so will reduce the data collection burden for hospitals. [15] In addition, this measure is not included in the hospital OQR program.

Because the SSI measure proposed by CMS does not apply to the most common ASC procedures, CMS should explore expanding this measure to frequent ASC procedures that involve incisions, such as cataract surgery and arthroscopic surgery. Once CMS has expanded the SSI measure, it should phase out the two infection control process measures listed above (prophylactic IV antibiotic timing and selection of prophylactic antibiotic) because they would no longer be necessary if ASCs were reporting SSI rates for a majority of their procedures. As discussed below, we also support the addition of structural and patient experience measures in the future.

Measuring surgical site infections

The importance of requiring ASCs to report SSIs is bolstered by evidence that lapses in infection control were common among a sample of ASCs in three states. [16] Measuring SSI rates could also be a way to encourage providers to collaborate and better coordinate care for ambulatory surgery patients. CMS's proposed measure, which has been endorsed by the NQF, tracks the percent of SSI events occurring within 30 days after the operative procedure if no implant is left in place, or within 1 year if an implant is in place *and* the infection appears to be related to the procedure. CMS proposes requiring ASCs to submit data related to infections that occur from January 2013 through June 2013. CMS has adopted this SSI measure for the hospital IQR program and proposed it for the hospital OQR program. The Commission supports aligning quality measures across

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[15] Centers for Medicare and Medicaid Services. 2011. Medicare hospital inpatient prospective payment system final rule. *Federal Register* 76 (August 18): 51610-51611.

[16] Schaefer, M.K., M. Jhung, M. Dahl, et al. 2010. Infection control assessment of ambulatory surgical centers. *Journal of the American Medical Association* 303, no. 22 (June 9): 2273–2279.

settings (such as ASCs, hospital outpatient departments, and physician offices) and across Medicare's quality reporting and payment systems.

However, we have concerns about CMS's proposed SSI measure. CMS proposes that ASCs would report this measure using the NHSN, which specifies the types of procedures that should be monitored (e.g., appendix surgery, cardiac surgery, and colon surgery). These procedure categories do not include the most common procedures performed in ASCs that involve incisions, such as cataract surgery or arthroscopy. Therefore, this SSI measure will probably not apply to many ASCs. Consequently, CMS should explore whether alternative SSI measures are available to track infections related to the most frequent ASC procedures that involve incisions.

Another issue relates to the process for ASCs to detect and report SSIs to NHSN. The CDC recommends that providers who participate in NHSN monitor SSIs through a combination of methods: Direct examination of patients' wounds during follow-up visits, review of medical records, surveys of surgeons, and surveys of patients. The CDC requires providers to report clinical information on each patient who receives one of the procedures using a standardized form or to download operating room data to NHSN. Providers must also submit clinical data on each patient who acquires an SSI using a standardized form. Because ASCs typically do not have an ongoing relationship with patients, it would likely be difficult for them to directly examine patients' wounds during follow-up visits. Therefore, CMS should instruct ASCs to conduct a follow-up phone call with patients, their caregivers, or their physicians within 30 days after the procedure to identify patients who have developed SSIs. ASCs should include this information in the medical record and submit it to NHSN. In addition, CDC should modify the NHSN to allow providers to submit all the required data using electronic medical records (EMRs). As more providers adopt EMRs, it should become less burdensome to track SSIs and report data to NHSN.

Measuring hospital transfers or admissions after an ASC procedure

CMS proposes to use a measure that tracks ASC patients who are transferred or admitted directly to a hospital (including a hospital emergency room) upon discharge from an ASC. This measure should be expanded to include patients who return home after the ASC procedure but are then admitted to a hospital shortly thereafter due to a problem related to the procedure. Including these patients in the measure would enable CMS to better track patients who experience serious complications or medical errors related to an ASC procedure. Because some patients are admitted to the hospital after returning home from an ASC, CMS should consider creative methods to track these adverse outcomes. For example, CMS could analyze claims data to look for patterns of hospital admissions that occur within a certain number of days of an ASC procedure, specifically focused on admissions for complications that are associated with the ASC procedure that was performed.

Other outcomes measures

The other three outcomes measures (patient fall; patient burn; wrong site, wrong side, wrong patient, wrong procedure, wrong implant) are patient safety indicators identified by the NQF as "serious reportable events," which are defined as errors in medical care that are clearly identifiable and measurable, usually preventable, serious in their consequences for patients, and that indicate a problem in a health care facility's safety systems. These patient-safety indicators were developed by the industry-sponsored ASC Quality Collaboration and have been endorsed by the NQF. Given that these measures were developed by an ASC industry coalition, it should be technically feasible for ASCs to report these indicators without an undue administrative burden.

Clinical process, structural, and patient experience measures

In addition to the five outcomes measures described above, we support requiring ASCs to report two infection control process measures in the first phase of the QRP:

- Prophylactic IV antibiotic timing
- Selection of prophylactic antibiotic: First or second generation cephalosporin

Prophylactic IV antibiotic timing assesses the rate of ASC patients who received IV antibiotics to prevent surgical site infection on time (within one or two hours prior to the incision). Selection of prophylactic antibiotic assesses the rate of patients with indications for a first or second generation cephalosporin prophylactic antibiotic who had an order for such an antibiotic; guidelines indicate that these antibiotics are effective for prevention of surgical site infections in most cases. These indicators are similar to measures that have been included in the hospital IQR and OQR programs and the physician quality reporting system (PQRS). Requiring the reporting of these measures by ASCs would harmonize use of these measures across four settings of care, a small but important step toward the goal of consistent quality measures across care settings. We believe that these measures would not impose a significant administrative burden on ASCs because they would be reported through the claims process using new quality data codes. CMS should explain whether these new codes would be reported with every claim for an ASC procedure or only if the adverse event has occurred. Once CMS has expanded the SSI outcome measure to include additional ASC procedures, it should phase out these two process measures because they would no longer be necessary if ASCs were reporting SSI rates for a majority of their procedures.

We also support CMS's proposal to add a new structural measure for reporting in 2013 based on the use of a safe surgery checklist. A safe surgery checklist would help ensure that safe practices are performed prior to administration of anesthesia, prior to incision, and prior to the patient leaving the operating room. Because CMS has proposed adding this measure to the hospital OQR program, adding it to the ASC program would help align measures across these settings. Because

ASCs would report whether they used a safe surgery checklist via a web-based tool, we do not expect that this measure would impose a substantial burden on ASCs.

CMS proposes to add another structural measure for reporting in 2013: Patient volume data for six broad categories of procedures (e.g., gastrointestinal, eye, nervous system). CMS cites evidence that the volume of surgical procedures—particularly high-risk procedures—is related to better patient outcomes. In addition, the NQF has adopted structural measures of patient volume for certain surgeries performed in inpatient settings, such as esophageal resection. However, the NQF has not adopted similar measures for outpatient procedures. Because the evidence of a link between facility volume and outcomes is primarily based on high-risk procedures, rather than the low-risk procedures commonly performed in ASCs, we do not believe that the volume of ASC procedures is a good proxy for ASC quality.[17] Moreover, adoption of this measure could lead ASCs to increase their volume to improve their performance on this measure, even though a link between the volume of outpatient surgery procedures and outcomes has not been demonstrated.

Measures of patient experience in ASCs are important and the Commission supports the development of a survey to measure patients' perceptions of their ASC care. Such a survey could be modeled after the existing CAHPS surveys for clinicians and groups and the CAHPS Surgical Care Survey.

FY 2014 Inpatient Hospital Value-Based Purchasing (VBP) Program

In addition to the hospital OPPS and ASC policies in the proposed rule, CMS also discusses technical proposals that would affect the FY 2014 Hospital Value-Based Purchasing (VBP) Program, such as baseline and performance periods, performance standards, and benchmarks for the VBP program measures. CMS also proposes the weighting that would be assigned to each measure domain, which is a key factor in determining a hospital's total performance score. For FY 2014, CMS proposes the following domain weights: outcome domain = 30 percent, clinical process of care domain = 20 percent, patient experience of care domain = 30 percent, and efficiency (defined by CMS as Medicare spending per beneficiary for an inpatient episode) = 20 percent.

Comments

We support CMS's proposal to give the outcome measure domain significant weight, which we previously stated (in our March 4, 2011 comment letter on the Hospital VBP program proposed rule) should be equal to or greater than the weight of the clinical process of care domain. We also support CMS's statement in the proposed rule that the agency will "propose increasing the weight for the outcome domain in subsequent fiscal years as more outcome measures become available," which we also suggested in our March comment letter.

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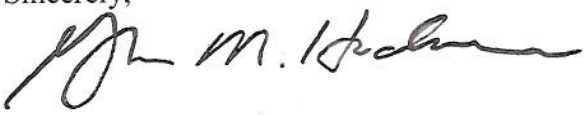
[17] ECRI Institute. 2010. *Hospital volume, surgeon volume, and operative mortality for six procedures: A systematic review*. Plymouth Meeting, PA: ECRI Institute Health Technology Assessment Information Service. August 3. Prepared for National Quality Forum.

Conclusion

MedPAC appreciates the opportunity to comment on the important policy proposals from CMS. The Commission also values the ongoing cooperation and collaboration between CMS and MedPAC staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact Mark E. Miller, MedPAC's Executive Director.

Sincerely,



Glenn M. Hackbarth, J.D
Chairman

GMH/dz/w